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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/697,351 | 10/29/2003 | Kenneth F. Buechler | 36671-716.302 | 7522 |
| 80984 7590 01/09/2009 Invemess Medical Innovations / WSGR Wilson Sonsini Goodrich & Rosati, P.C. 650 Page Mill Road Palo Alto, CA 94304 | | | | |
| EXAMINER ALEXANDER, LYLE | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1797 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 01/09/2009 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/697,351

Applicant(s)

BUECHLER, KENNETH F.

Examiner

Lyle A. Alexander

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date 11/5/08
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 3-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 and 1-24 of copending Application No. 11/022, 297 and 10/792,258 respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because all are directed to an assay device for detecting one or more ligands.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 and 3-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,143,576. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims a non-porous surface comprising particles immobilized to the surface where the particles range in size from about 1nm to 100nm (claim 8) which is indistinguishable from the pending claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original specification does not appear to specifically teach the "assay device does not comprise a second surface positioned ...". Clarification could be achieved if Applicant were to specifically point out where in the original disclosure this limitation is taught.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The invention is directed to forming capillary channels to transport the sample. It is not clear how the sample could be transported without a second surface that forms a capillary channel. Additionally, the meets and bounds of the claim. No structure is claimed that further limits the subject matter of any one of the previous claims 1-5.

Apparently, this claim is directed to claiming the absence of a structure (e.g. absence of a capillary space) and is not readily understood.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Findlay et al. (USP 5,514,550) or Wu (USP 5,387,510).

In light of the above 35 USC 112 issues, the claims are best understood as a nonporous surface with immobilized particles that have binding receptors.

The effective filing date of this application has been determined as 7/11/00 because the parent patents 6,156,270, 6,143,576 and 6,271,040 does not contain the presently claimed "nonporous" surface.

Findlay et al. teach an assay device having a nonporous surface (see col. 14 lines 9+) with particles immobilized to the surface. Column 6 lines 31-41 teach the particles are in the range of 0.1-10 microns and preferably between 0.1 and 5 microns (also see claim 3). The claimed protrusions extending between 1 microns to 0.5mm has been read on the taught immobilized particles. Column 6 lines 41-55 teach the claimed materials of the particles. Example 2 in column 13 expressly teaches the particles are made of polystyrene. The surface of Findlay et al. would have been expected to have at least one depression/protrusion between 1nm and 0.5mm as a manufacturing

imperfection. The Office has read this on claim 3 "... a textured surface comprising one or more depressions and/or protrusion extending between 1nm and 0.5mm... ".

Wu teaches a nucleic acid amplification kit. Column 10 lines 47-64 teach the surface can be nonporous. Column 9 lines 3-9 teach the particles immobilized on the surface could be from 0.01-10 microns. Column 9 lines 38-50 teach the particles can be made of polystyrene. The claimed protrusions extending between 1 microns to 0.5mm has been read on the taught immobilized particles. The surface of Wu et al. would have been expected to have at least one depression/protrusion between 1nm and 0.5mm as a manufacturing imperfection. The Office has read this on claim 3 "... a textured surface comprising one or more depressions and/or protrusion extending between 1nm and 0.5mm... ".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Findlay et al. or Wu et al. in view of Oosta et al.(USP 5,478,751).

See Findlay et al. and Wu et al. *supra*.

These references are silent to placing a second surface at a capillary distance from the nonporous surface.

Oosta et al. teach an immunodiagnostic device that binds target ligands. In column 7 lines 20-38, Oosta et al. teaches a cover on the device to protect the binding reagents. Additionally, column 6 lines 37-55 teach the device is a capillary flow device and all of the dimensions are such to promote capillary flow. In light of the teachings of column 6, the Office has read Oosta et al. as teaching the cover taught in column 7 is spaced "... at a capillary forming distance ..." as presently claimed.

It would have been within the skill of the art to modify Findlay et al. or Wu et al. and provide a second surface, at a capillary forming distance, to protect the binding reagents.

Response to Arguments

Applicant's arguments filed 11/5/08 have been fully considered but they are not persuasive.

Applicant states the cited prior art does not teach the claimed "antibodies or fragments thereof immobilized to particles ...". Findlay et al. clearly teach in column 5 lines 1-19 and in column 7 line 24 antibodies bound to the particles which is indistinguishable from the instant claims. Applicant further states Findlay et al. and Wu

et al. require additional antibodies, probes, binders, etc. These remarks are not commensurate in scope with the pending claims that have open language (e.g. comprising) and do not exclude the presence of additional probes, binder, etc. The Office maintains the instant claims have been properly read on the pending claims.

Applicant traverses 35 USC 103 rejections over Oosta on the grounds Oosta does not qualify as prior art and does not teach "particles that comprise antibodies ...". The Office maintains Oosta qualifies as prior art for the put forth in the 8/17/07 Examiner's Answer. Additionally, Oosta is not being applied to teach the use of antibodies, etc., but rather the spacing of two layers to form a capillary space for the fluid to flow.

Conclusion

This is a RCE of applicant's earlier Application No. 10/697,351. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Tuesday and Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lyle A Alexander/
Primary Examiner, Art Unit 1797

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